Dr. SCHMIDT. If there are any in that category, it would be extremely small, and there may be none as yet at all.

Senator NELSON. What I am trying to get at is a definition. When you say almost 6,000 ineffective drugs have been removed from the marketplace, I take it that there are a number of drugs that were classified "possibly effective," and FDA has required in accordance with the statute, that the manufacturers submit substantial evidence of effectiveness. And if they cannot do so, that drug that was classified "possibly effective" then becomes classified "ineffective."

Is that correct?

Dr. SCHMIDT. Well, yes, sir. Generally where we are now in the process is that the clearly ineffectives for which there were no data supplied have generally been removed from the market. We are now in the process of evaluating data submitted to us by firms for drugs that have been classified as possibly or probably effective.

In most instances—and this point relates to an earlier thing you heard about, and that is the delay in our implementing the study and the court order that we are currently under—there are a number of mechanisms that come under the heading of due process that caused delay in our taking action against drugs.

For example, we would propose to remove drugs from the market. This proposal may be challenged, and, indeed, we will probably have to run a great number of hearings and probably then be in court a number of times before we can finish up this job.

Senator NELSON. You mean the issue involved will be a difference of opinion between the manufacturer and the FDA as to the adequacy of the evidence to support the claim of efficacy?

Is that what you are saying?

Dr. SCHMIDT. Partly the argument should be scientific, and partly they will be procedural. But in general we are going down a carefully constructed path that will include hearings before we remove some of the drugs that are in these intermediate categories for which conclusive data of efficacy has not been submitted.

Senator NELSON. Please proceed.

Dr. SCHMIDT. I mntioned that many products not previously covered by NDAs have been required to submit abbreviated NDAs, and as Dr. Crout has just mentioned, before such applications are approved, we require compliance with GMP regulations. As in the case of NDA submissions, this is determined by a very thorough plant inspection. This program has greatly increased our inspection activities in small and medium-size firms in the past and has resulted in substantial improvement in compliance with the requirements of GMP regulations.

The DESI program has also improved and promoted the exchange of information between FDA and other health agencies regarding drug efficacy status and does have an influence on purchasing policies of various Government agencies. The impact of the program is remarkably broad. You heard some of it earlier from the previous testifier.

The Secretary of DHEW has directed that Federal funds will not be expended for the purchase of drugs classified under the DESI